

REMARKS

Claim 1 is currently amended. Claims 11 and 13 are canceled without prejudice. Claims 10 and 27-43 were previously canceled without prejudice. Accordingly, claims 1-9, 12, 14-26, and 44 are pending in this application. Reconsideration of the pending claims is respectfully requested in view of the following remarks.

Examiner Interview Summary

Applicant thanks the Examiner for the courtesy of a telephone interview on January 18, 2011, with Applicant's representative, Gregory M. Taylor. During the interview, amendments to claim 1 corresponding to those presented herein were discussed in relation to the cited prior art. The Examiner generally agreed that amended claim 1 was not obvious over the cited references, but that further consideration would be required.

Rejections Under 35 U.S.C. § 103

Claims 1, 2, 5, 7-11, 13-16, 23, and 24 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Hammar et al. (U.S. Patent No. 4,786,446) in view of Poler (U.S. Patent No. 4,402,579), and in view of Lee (U.S. Patent No. 4,619,793) and evidenced by Sakurada (CRC Press; 1985; 9780824774349). Applicant respectfully traverses.

Claim 1, as amended, recites a method of producing a plurality of soft contact lenses, comprising:

- A. providing a sheet of solid, substantially dry material;
- B. forming said material into a plurality of shaped lens blanks through controlled application of physical force to the material by compression of the material between two forms or platens in a process selected from the group comprising *thermoforming or vacuum forming or pressing or hot moulding or cold moulding or compression moulding*; and
- C. hydrating said plurality of shaped lens blanks;

wherein at least immediately subsequently to said physical forming step B, said plurality of shaped lens blanks remain at least partially attached to the sheet of material and the *sheet is used as a transport medium or carrying mechanism for said plurality of shaped lens blanks.*

Claim 1 is amended to incorporate subject matter from claims 11 and 13, now canceled.

Initially, Applicant submits that there is no teaching, suggestion, or motivation for combining the teachings of Hammar and Poler.

Hammar discloses a process in which individual lens shaped blanks are formed by thermoprocessing thermoplastic polymeric precursors to hydrogels into molded lens articles. The lenses of Hammar are each formed individually, there being no disclosure of the formation of a plurality of blanks from a single sheet of material or that the lenses remain attached to a sheet after formation.

Poler teaches that an array of lens-and-haptic contact lens specimens can be formed by etching a sheet of material. The process of Poler is primarily directed to the formation of “hard” contact lenses of a non-breathable glass or plastic material (col. 2, lines 43-45) that require an open fenestrated region to allow the cornea to breathe (col. 2, lines 53-57). In contrast, the presently claimed invention is directed to producing soft contact lenses that are hydrated with water. The presence of the water allows the cornea to breathe through the lens.

Although in neighboring fields, hard and soft contact lenses are very different types of products that require different manufacturing processes. Therefore, technology directed to the production of hard contact lenses is neither directly transferrable to processes for the manufacture of soft lenses nor would the person of ordinary skill in the art consider it obvious to apply techniques used in hard contact lens manufacturing processes to soft contact lens manufacturing processes.

Thus, it would not have been obvious to apply techniques known from Poler to the formation of soft contact lenses, nor combine the other teachings of Poler with Hammar or other documents in the soft contact lens field.

In addition, Applicant submits that it would not have been obvious from the teachings of the cited references that a sheet of material can be used in forming a “*plurality of shaped lens blanks through controlled application of physical force*” in a process selected from “*thermoforming or vacuum forming or pressing or hot moulding or cold moulding or compression moulding*” and that the “*sheet is used as a transport medium or carrying mechanism for said plurality of shaped lens blanks*” as recited in claim 1.

If it were assumed, *arguendo*, that the array of lens-and-haptic contact lens specimens of Poler were equivalent to a sheet, such a structure could not be formed with the moulding processes recited in claim 1.

Furthermore, even if the person of ordinary skill were to consider Poler with a view to improving methods of making soft lenses such as the method of Hammar, they would still not arrive at the presently claimed invention. As set out below, various features recited in claim 1 are not taught or suggested in Hammar or Poler.

(1) Plurality of shaped lens blanks

Step B of claim 1 requires the formation of a “*plurality of shaped lens blanks through controlled application of physical force*” to a sheet of material.

In contrast Poler teaches a two step process for the formation of an array of lens shaped blanks from a flat stock sheet. In one step, the peripheral contour of the ultimate central lens as well as the haptic structure which is integral with the central lens are formed. Then in a separate step, the lens surface curvature is developed (col. 1, lines 44 to 54). The peripheral contour is obtained in Poler by an etching step that creates, from a flat stock sheet 12, an array of edge interconnected partially completed specimens where the nested partially completed specimens are connected by a severable tie (*see* Figs. 10 and 11; col. 4, lines 16-44). Then, in order to finish the lens, the partially completed specimens are positioned in a forming die to shape the lens by plastic deformation under compressional pressure (*see* col. 4, lines 48-57 and Fig. 5).

Thus, the etching step of Poler does not produce a “*plurality of shaped lens blanks*” as recited in claim 1, but rather a plurality of flat partially completed blank specimens which are then processed into a plurality of lens shaped blanks in a subsequent lens finishing step. There is nothing in Poler to suggest that those two steps could be combined, let alone that the etching step, which is an essential feature of the process of Poler could be done away with.

(2) Formation via a compression technique

As Poler teaches how to obtain an array of edge interconnected specimens by an etching technique in which sheet material is eroded way, it would not have been obvious how such an array could be formed by “*compression of the material between two forms or platens in a process selected from the group comprising thermoforming or vacuum forming or pressing or hot moulding or cold moulding or compression moulding*” as recited in claim 1. In such moulding processes, it is inevitable that excess material will be extruded from out of the mould and onto the adjacent regions. However, in an edge interconnected array such as disclosed in Poler there are no available adjacent regions onto which the excess material could be extruded. Therefore, the erosion technique for forming the peripheral shape of a lens in Poler could not simply be substituted by a compression technique without making further inventive modifications to the process of Poler.

(3) Partial attachment of lens shaped blanks to the sheet

Poler teaches that a sheet of material is etched so as to form an array of edge interconnected lens-and-haptic specimens. The lens-and-haptic specimens are extraocular devices for contact application to the cornea (*see col. 1, lines 5-9*) that are multicomponent structures comprising a central lens 10 and an integral haptic structure 11, which is used for supporting the central lens in the correct position on the eye (*see*

col. 2, lines 35-40). The lens-and-haptic structure would, therefore, be recognized by a person of ordinary skill in the art as together forming a single contact lens specimen.

Poler teaches that unmasked parts of the sheet are eroded away, the etching proceeding fully through the thickness of the sheet of material such that the intermediate product is severed from the surrounding sheet material (*see* col. 3, lines 62-65). In the edge interconnected situation, no part of the sheet remains other than the array of partially completed lens-and-haptic specimens, which are interconnected via a severable tie, and which are handled together (*see* col. 4, lines 18-47).

Thus, there is nothing in Poler to suggest that a plurality of partially completed or completed specimens “*remain at least partially attached to the sheet of material*” as recited in claim 1.

(4) Sheet used as transport medium for lens shaped blanks

Poler teaches that particular arrangements of linear arrays of severably connected lens specimens permits automatic handling (*see* col. 4, lines 44-47). In contrast, claim 1 recites that the sheet itself is used as a “*transport medium or carrying mechanism*” which has the advantage that the automatic handling system does not handle the lens specimens directly, and thus lessens the chance of the soft contact lens specimens being damaged.

Applicant respectfully disagrees with the Examiner’s finding that col. 4, line 45 of Poler teaches that a sheet is used for a transport medium or carrying mechanism. This passage states “the arrangement of Fig. 11 permits automatic handling of linear arrays of severably interconnected specimens.” The preceding passage in col. 4, lines 18 to 22 states that in “the individually separated specimen situation, each item must be handled separately, but in the *edge-interconnected situation the individual specimens* may more readily be handled by mass lens-finishing techniques.” (Emphasis added). Thus, Poler discloses the handling of an array of interconnected *individual* specimens together, not a plurality of specimens attached to a sheet. Figure 11 of Poler shows that the lens-haptic specimens are not attached to a sheet but rather are attached to one another at 25’ and 26’.

Applicant submits that because of the delicate nature of the array of interconnected lens-haptic specimens of Poler, such an array could not be used itself as a “*transport medium or carrying mechanism*” for the lenses without causing substantial damage to the array.

Lee discloses compressing a dried film of polyvinyl alcohol between two mold parts of a lens replica shape to form, anneal, and separate from the film, a lens (*see col. 10, lines 54-65*). Although Lee discloses the formation of a lens through controlled application of physical force by compression of the material between two molds, this feature is not disclosed in a manner that would be compatible with a process step in which “*shaped lens blanks remain at least partially attached to the sheet of material*” as recited in claim 1. Rather, Lee makes it clear that the compression step separates the formed lens from the film (*see col. 10, lines 62-65*), there being no disclosure of a step that could form a lens that remains at least partially attached to a sheet. Thus, it would not have been obvious to apply the foregoing teachings of Lee to a process such as disclosed in Poler. The teachings of Poler and Lee are incompatible in the sense that Poler teaches that lenses should remain attached to one another after formation and Lee teaches against leaving the lens attached to any other items following the lens formation step, but instead that the lenses should be separated into discrete items.

Furthermore, the skilled person could not simply substitute the etching and subsequent shaping steps of Poler with the thermoforming step of Lee in order to produce the array of edge interconnected lenses. In the molding process of Lee, a concave mold and a matching convex mold is used to compress the film of material (*see col. 10, lines 54-61*) with excess material inevitably being extruded out from between the two molds to the sides. Therefore, it would not be possible to obtain the array of Poler using the thermoforming process of Lee as the material that would be extruded from out of the molds would spill onto neighboring lenses. In order to use a molding process to form an edge interconnected array of lens blanks it would be necessary to invent a complicated new molding process such that material is not extruded to the sides of the mold but

instead is extruded elsewhere, and then employ a deburring step to ensure that the lens surfaces are smooth. Alternatively, the person of ordinary skill in the art would have to come to the realization that the edge interconnected array structure of Poler could not be used and instead devise a different arrangement of blanks that can accommodate material extruded from the mold. Either of these possibilities require inventive activity and are not mere simple substitution to obtain predictable results that would be obvious.

Despite their incompatibilities, if the person of ordinary skill in the art were to consider combining the teachings of Poler, relating to hard contact lenses, with that of Hammar and Lee, which relate to soft contact lenses, such person would still need to exercise inventive activity. Major modifications to the processes disclosed in these references would be required to make them compatible. For example, the simple substitution of the etching and compression steps of Poler with a single molding step of Hammar and/or Lee would not be possible without major modification to the teachings of these references. As such, a person skilled in the art would have no technological motivation to combine the teachings of the cited references.

Further, even if the teachings of the cited references were to be combined with the teachings of Lee as proposed by the Examiner, not all of the limitations of claim 1 are met. In particular, the combined teachings of the references collectively fail to teach a plurality of lens shaped blanks formed from a sheet of material that remain at least partially attached to the sheet after formation, and also collectively fail to teach use of a sheet as a transport or carrying mechanism for transporting the plurality of blanks.

In addition, the teachings of Sakurada do not cure the deficiencies of the other cited references.

Accordingly, claim 1 would not have been obvious over the cited references.

Since claims 2, 5, 7-11, 13-16, 23, and 24 depend from claim 1 and thus include all the limitations of claim 1, these dependent claims would also not have been obvious over the cited references for at least the same reasons as claim 1.

Applicant therefore respectfully requests that the rejection of claims 1, 2, 5, 7-11, 13-16, 23, and 24 under 35 U.S.C. § 103(a) be withdrawn.

Claims 3 and 4 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Hammar in view of Poler and Lee, and further in view of Hassan et al. (Publication: *Water Solubility Characteristics of Poly(Vinyl Alcohol) and Gel Prepared By Freezing/Thawing Processes*, Water Soluble Polymers; Plenum Press, 1998). Applicant respectfully traverses.

Claims 3 and 4 depend from claim 1 and thus include all the limitations of claim 1. As discussed previously, claim 1 would not have been obvious over Hammar in view of Pole and Lee. Adding the teachings of Hassan as proposed by the Examiner does not overcome the deficiencies of the other cited references.

As a result, claims 3 and 4 would not have been obvious over the cited references.

Applicant therefore respectfully requests that the rejection of claims 3 and 4 under 35 U.S.C. § 103(a) be withdrawn.

Claim 6 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Hammar in view of Poler and Lee, and further in view of Iwaseya et al. (Publication: *Effect of Degree of Saponification on Properties of Films Obtained from PVA/NaCl/H₂O*, J Mater Sci 41 (2006). Applicant respectfully traverses.

Claim 6 depends from claim 1 and thus includes all the limitations of claim 1. As discussed previously, claim 1 would not have been obvious over Hammar in view of Poler and Lee. Adding the teachings of Iwaseya as proposed by the Examiner does not overcome the deficiencies of the other cited references.

As a result, claim 6 would not have been obvious over the cited references.

Applicant therefore respectfully requests that the rejection of claim 6 under 35 U.S.C. § 103(a) be withdrawn.

Claim 12 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Hammar in view of Poler and Lee, and further in view of Miller et al. (U.S. Patent No. 4,652,721). Applicant respectfully traverses.

Claim 12 depends from claim 1 and thus includes all the limitations of claim 1. As discussed previously, claim 1 would not have been obvious over Hammar in view of Poler and Lee. Adding the teachings of Miller as proposed by the Examiner does not overcome the deficiencies of the other cited references.

As a result, claim 12 would not have been obvious over the cited references.

Applicant therefore respectfully requests that the rejection of claim 12 under 35 U.S.C. § 103(a) be withdrawn.

Claims 17 and 18 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Hammar in view of Poler and Lee, and further in view of LeVa (U.S. Patent No. 5,166,528). Applicant respectfully traverses.

Claims 17 and 18 depend from claim 1 and thus include all the limitations of claim 1. As discussed previously, claim 1 would not have been obvious over Hammar in view of Poler and Lee. Adding the teachings of LeVa as proposed by the Examiner does not overcome the deficiencies of the other cited references.

Hence, claims 17 and 18 would not have been obvious over the cited references.

Applicant therefore respectfully requests that the rejection of claims 17 and 18 under 35 U.S.C. § 103(a) be withdrawn.

Claim 19 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Hammar in view of Poler and Lee, and further in view of Voss et al. (U.S. Patent Application Pub. No. 2004/0112008). Applicant respectfully traverses.

Claim 19 depends from claim 1 and thus includes all the limitations of claim 1. As discussed previously, claim 1 would not have been obvious over Hammar in view of

Poler and Lee. Adding the teachings of Voss as proposed by the Examiner does not overcome the deficiencies of the other cited references.

As a result, claim 19 would not have been obvious over the other cited references.

Applicant therefore respectfully requests that the rejection of claim 19 under 35 U.S.C. § 103(a) be withdrawn.

Claims 20 and 21 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Hammar in view of Poler and Voss, and further in view of Jux (U.S. Patent No. 6,474,465). Applicant respectfully traverses.

Claims 20 and 21 depend from claim 1 and thus include all the limitations of claim 1. As discussed previously, claim 1 would not have been obvious over Hammar in view of Poler and Voss. Adding the teachings of Jux as proposed by the Examiner does not overcome the deficiencies of the other cited references.

Thus, claims 20 and 21 would not have been obvious over the cited references.

Applicant therefore respectfully requests that the rejection of claims 20 and 21 under 35 U.S.C. § 103(a) be withdrawn.

Claims 22 and 44 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Hammar in view of Poler and Lee, and further in view of Herbrechtsmeier et al. (U.S. Patent No. 6,113,817). Applicant respectfully traverses.

Claims 22 and 44 depend from claim 1 and thus include all the limitations of claim 1. As discussed previously, claim 1 would not have been obvious over Hammar in view of Poler and Lee. Adding the teachings of Herbrechtsmeier as proposed by the Examiner does not overcome the deficiencies of the other cited references.

As a result, claims 22 and 44 would not have been obvious over the cited references.

Applicant therefore respectfully requests that the rejection of claims 22 and 44 under 35 U.S.C. § 103(a) be withdrawn.

Claims 25 and 26 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Hammar in view of Poler and Lee, and further in view of Biel et al. (U.S. Patent Application Pub. No. 2002/0163638). Applicant respectfully traverses.

Claims 25 and 26 depend from claim 1 and thus include all the limitations of claim 1. As discussed previously, claim 1 would not have been obvious over Hammar in view of Poler and Lee. Adding the teachings of Biel as proposed by the Examiner does not overcome the deficiencies of the other cited references.

Hence, claims 25 and 26 would not have been obvious over the cited references.

Applicant therefore respectfully requests that the rejection of claims 25 and 26 under 35 U.S.C. § 103(a) be withdrawn.

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CONCLUSION

Applicant respectfully submits that the pending claims are in condition for allowance and notification to that effect is earnestly requested. If necessary, please charge any additional fees or credit overpayments to Deposit Account No. 502432.

If the Examiner has any questions or concerns regarding this application, please contact the undersigned at the telephone number listed below.

Respectfully submitted,

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